

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
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**REPLY IN SUPPORT OF MOTION TO EXCLUDE  
GENERAL-CAUSATION TESTIMONY OF NEERAJ KOHLI, M.D., M.B.A**

While Dr. Kohli is a well-credentialed physician, Ethicon requests that the Court exclude those opinions of his that are unreliable, irrelevant, unhelpful, or misleading under Rules 702 and 403, and *Daubert*. Plaintiffs' arguments in opposition do not cure these deficiencies. More specifically, Plaintiffs:

- are unable to controvert the cases throughout the country, including the Fourth Circuit, holding that evidence of alternative surgical techniques is irrelevant to design defect claims;
- are unable to point to even a single reliable basis for Dr. Kohli's complication-rate opinion;
- concede that Dr. Kohli's clinical-studies-prediction opinion is inadmissible;
- fail to demonstrate a reliable basis for Dr. Kohli's opinion concerning TVT-O's appropriateness for certain patient populations;
- do not distinguish Dr. Kohli's opinions concerning the competency of other physicians from essentially identical opinions the Court has previously excluded as irrelevant under the same record and arguments; and
- suggest that Dr. Kohli's opinions are based on his personal experience when in fact they are purely prohibited opinions concerning knowledge, motive, intent, and a narrative review of Ethicon's company documents.

Accordingly, as explained more fully below, Ethicon respectfully asks that the Court exclude the opinions of Dr. Kohli as set forth in its Memorandum. *See* Defs.’ Mem. (Dkt. 1995).

### **ARGUMENTS AND AUTHORITIES**

#### **I. Dr. Kohli’s Design Defect Opinions Are Contrary to Uncontroverted Fourth Circuit Precedent Addressing the Same Arguments and Record.**

Dr. Kohli’s opinions conflating surgeons’ discretion and competency in the use of TVT-O with design defects misunderstands and contorts product liability law. All implantable medical devices necessarily require surgery for their use. But no physician was “required” to utilize an allegedly “difficult” transobturator surgical technique with TVT-O. *See* Pls.’ Opp’n (Dkt. 2178) at 4-6. Nor is a surgeon’s competency or difficulty in implanting TVT-O relevant. *See* Defs.’ Mem. (Dkt. 1995) at 8-9 (discussing *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923 (S.D.W. Va. July 8, 2014). Rather, “[i]t is well established that a medical device manufacturer is not responsible for the practice of medicine.” *Sons v. Medtronic Inc.*, 915 F. Supp. 2d 776, 783 (W.D. La. 2013). “For physician-prescribed drugs and medical devices, the physician ‘is in the best position to understand the patient’s needs and assess the risks and benefits of a particular course of treatment.’” *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163 (4th Cir. 1999).

That a plaintiff’s surgeon could have implanted the TVT-O mesh using a different surgical technique (*i.e.*, implanted TVT), or chosen not to use any mesh at all, does not demonstrate a design defect in TVT-O. In *Talley*, the Fourth Circuit Court of Appeals made clear that these assertions “questioned the medical judgment of doctors,” and might be relevant in a malpractice suit against the doctor, but not a suit against the manufacturer. *Id.* at 162. Surgical alternatives using the same device “[do] not indicate any design flaw.” *Id.* Indeed courts throughout the country have rejected Plaintiffs’ proposition (*see* Defs.’ Mem. (Dkt. 1995) at 3-

4), and Plaintiffs cite no case law that supports their erroneous argument to the contrary (*see* Pls.’ Opp’n (Dkt. 2178) at 4-5).

There is no conflict with this Court’s prior rulings, as Plaintiffs argue. *See* Pls.’ Opp’n (Dkt. 2178) at 5-6. This Court in *Tyree* addressed whether the expert’s surgical-technique opinions were reliable, not whether they were relevant to support a design-defect claim. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 560 (S.D.W. Va. 2014). The Court did not address to which issues this testimony was relevant and irrelevant. *Id.* Plaintiffs’ reliance on *Huskey* is likewise inapposite because the Court there considered the *reliability* of Dr. Blaivas’s opinions, not their relevancy. Ex. 1, Trial Tr. at 16:1-6, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D.W. Va. Aug. 28, 2014).

Ethicon has not argued here that testimony about alternative surgical techniques is irrelevant as to all claims. Rather, it asks the Court to rule consistent with Fourth Circuit and courts around the country that, while alternative-surgical-technique opinions may support other claims, they do not support design-defect claims in general and cannot support that the TVT-O here in particular is defective in design. *See Talley*, 179 F.3d at 162; *see also* Defs.’ Mem. (Dkt. 1995) at 2-5. This opinion runs counter to established and uncontroverted Fourth Circuit precedent, and therefore is irrelevant to a design-defect claim.<sup>1</sup>

Dr. Kohli’s surgical-technique design-defect opinions are simply irrelevant under this established case law and therefore should be excluded on relevancy grounds. *See Daubert*, 509

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<sup>1</sup> Plaintiffs’ argument that the cases disallowing surgical alternatives to support design defect claims were decided at summary judgment is a distinction without a difference. *See* Pls.’ Opp’n (Dkt. 2178) at 7. If the opinion is offered to support an improper basis for liability, then it violates the “relevance” or “fit” requirement under *Daubert*. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591-92 (1993).

U.S. at 591-92 (explaining that an expert's opinion must "fit" the relevant inquiry, and that scientific validity for one purpose is not necessarily scientific validity for other purposes).

## **II. Articles About Other Devices Do Not Support a Complication Rate Opinion for TVT-O, Especially a Purely Subjective Opinion.**

Whether couched as one or two opinions, Dr. Kohli's reliance solely on haphazard articles about other devices and surgical techniques does not suffice as proper methodology for a reliable TVT-O complication-rate opinion. *See* Defs.' Mem. (Dkt. 1995) at 5-6. And Plaintiffs do not deny that Dr. Kohli's opinion is based on a blatant and unsystematic extrapolation of complications reported as to other devices. *See* Pls.' Opp'n (Dkt. 2178) at 8-9. Plaintiffs simply claim that Rule 702 as interpreted by the Court permits this type of flawed methodology. *Id.* It does not.

In *Eghnayem*, the Court excluded Dr. Margolis's complication-rate opinion because it was based on assumptions, not reliable methodology. *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 677 (S.D.W. Va. 2014). In *Tyree*, the Court excluded Dr. Margolis's Xenform complication-rate opinion in part because he did not cite a single study involving Xenform slings. *Tyree*, 54 F. Supp. 3d at 523. And in *Huskey*, the Court excluded Dr. Blaivas's complication-rate opinion because he did not explain his methodology. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 721 (S.D.W. Va. 2014). Dr. Kohli's complication-rate opinion suffers from all of these same flaws because he did not provide support from the TVT-O literature or his surgical experience, and he did not explain his methodology. Thus, this Court has routinely rejected—not endorsed—these types of flawed methodologies and their resultant unreliably based complication-rate opinions.

Plaintiffs misconstrue *Huskey* and *Winebarger*. In *Huskey*, the expert's failure to cite to specific TVT-O studies was inconsequential because the opinion related to under-reporting of

mesh complications generally, not solely for TVT-O. *Huskey*, 29 F. Supp. 3d at 720. Further, the expert relied upon several scientific studies that were directly on point. *Id.* Here, Dr. Kohli's opinion *does* relate specifically to TVT-O, and he does *not* cite to several on-point studies. In *Winebarger*, the expert was permitted to render safety and efficacy opinions based on his review of the literature and personal experience with the relevant products and procedures. *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at \*34 (S.D.W. Va. Apr. 24, 2015). The Court found that the lack of a direct-comparison study between the product and nonmesh procedures did not render the methodology behind the opinion unreliable. *Id.* Dr. Kohli not only lacks any direct-comparison study, but he also fails to provide relevant literature, surgical experience, or any other basis for his opinion. His opinion is wholly unsupported, and should therefore be excluded. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145-46 (1997).

Dr. Kohli's TVT-O complication-rate opinion remains subjective, over-general, and unsupported; it amounts to nothing more than his *ipse dixit* or his personal belief, and should therefore be excluded.

### **III. Plaintiffs Do Not Contest the Unreliability of Dr. Kohli's Clinical- Studies-Prediction Opinion.**

The Court should grant Ethicon's request to exclude Dr. Kohli's clinical studies predictions opinion based on Plaintiffs' representation that no such opinion will be offered at trial. *See* Pls.' Opp'n (Dkt. 2178) at 9.

### **IV. Dr. Kohli's Opinion Concerning TVT-O's Appropriateness for Certain Patient Populations Remains Unsupported and Unhelpful.**

Plaintiffs inexplicably cite to a portion of Dr. Kohli's expert report addressing his surgeon-training opinions to suggest that he supported his opinions two pages later concerning TVT-O's appropriateness for certain patient populations. *Compare* Pls.' Opp'n (Dkt. 2178) at 10 (citing Kohli Report at 33) *with* Defs.' Mem. (Dkt. 1995) at 7 (citing opinions in Kohli Report at

35). Yet the surgeon-training opinions expressed by Dr. Kohli have nothing to do with the marketing opinions challenged here, nor does the surgeon-training portion of his report offer support for this challenged marketing opinion.

Even if, as Plaintiffs claim, Dr. Kohli relied upon internal company documents, the opinion would still be unhelpful under the Court's ruling in *Edwards*. In *Edwards*, the Court determined that the jury was capable of interpreting the company documents for themselves and required no expert interpretation. *Edwards*, 2014 WL 3361923, at \*10. Thus, Dr. Rosenzweig's opinion, which was essentially identical to Dr. Kohli's opinion here, was unhelpful and inadmissible. *Id.* Dr. Kohli's "one-size-fits-all" marketing opinion<sup>2</sup> should therefore be excluded as well.

**V. Dr. Kohli's Surgeon-Competence Opinions are Irrelevant and Misleading Regardless of the Purpose for Which They are Offered.**

The Court has already determined that opinions addressing the competence of other surgeons in implanting TVT-O, including the effect of the trocar design on surgeon technique, are irrelevant and unhelpful to the jury. *Edwards*, 2014 WL 3361923, at \*17. Contrary to Plaintiffs' assertion that these are mere design-defect opinions, Dr. Kohli's report is replete with references to surgeons allegedly experiencing difficulty with implanting TVT-O just like the opinions excluded in *Edwards*. *See* Defs.' Mem. (Dkt. 1995) at 8-9 (citing Kohli Report at 9, 25, 32). And surgical technique difficulties nonetheless do not constitute design defects for the reasons discussed above. *See also Bogle v. Sofamor Danek Group, Inc.*, No. 95-8646, 1999 WL

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<sup>2</sup> Plaintiffs' discussion of Dr. Kohli's trocar-trajectory opinion is inapposite because Ethicon does not challenge that opinion as unreliable for lack of support, or for improper citation to company documents. Rather, Dr. Kohli's trocar opinion should be excluded because: (1) it constitutes an improper alternative-surgical-technique opinion if offered to prove design defect, and (2) it is irrelevant as an opinion concerning physician competency. *See* Defs.' Mem. (Dkt. 1995) at 2-5, 8-9.

1132313, at \*4 (S.D. Fla. Apr. 9, 1999) (finding claim that device should have been designed to be less difficult to implant did not identify a defect in the product, but rather that it was a product reserved to a top-rate surgeon).

Plaintiffs' argument provides no basis for the Court to depart from its earlier ruling. *See, e.g., Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at \*23 (S.D.W. Va. May 6, 2015) (adhering to the Court's earlier ruling where the expert's rejected opinions were unchanged from those already addressed). Nor do Plaintiffs offer any argument in opposition that Dr. Kohli's physician-competency opinions fail under Rule 403.

Accordingly, Dr. Kohli's surgeon-competency opinions should be excluded.

**VI. Plaintiffs Disregard the Court's Firm Rulings That Statements Concerning Knowledge, Motive, Intent, and a Narrative Review of Documents are Inadmissible.**

Although Plaintiffs claim that Dr. Kohli will not offer opinions concerning Ethicon's intent, motives, or state of mind, they suggest that Dr. Kohli's opinions are nonetheless admissible because they are "based largely on his clinical observations or his personal experience." Pls.' Opp'n (Dkt. 2178) at 13. Yet a review of Dr. Kohli's opinions cited by Ethicon reveals that these opinions intrude precisely in the manners expressly prohibited by the Court. *See* Defs.' Mem. (Dkt. 1995) at 10-11. If these "opinions" were based largely on Dr. Kohli's clinical observations and personal experience, he would not need to refer extensively to company documents, and particularly those that make no mention of him.

Further, in the limited times Dr. Kohli addresses his personal involvement, he offers subjective feelings about the events. *See, e.g., id.* at 10 (referring to Dr. Kohli's self-described "sense" and "feelings" about Ethicon and TVT-O history). Such subjective beliefs are not valid expert opinions, and should be excluded accordingly. *Daubert*, 509 U.S. at 590.

## CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General Causation Testimony of Neeraj Kohli, M.D., M.B.A., and limit his opinions for the reasons stated above and in its memorandum in support of its motion.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on May 16, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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